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JUL 22 2005

PTO/SB/21 (09-04)

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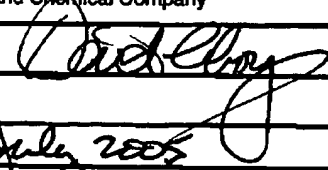
Application Number	09/873,505
Filing Date	June 04, 2001
First Named Inventor	CAO, Hongjie et al.
Art Unit	1617
Examiner Name	YU, Gina C.
Attorney Docket Number	1928.PC

## ENCLOSURES (Check all that apply)

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| <input checked="" type="checkbox"/> Fee Transmittal Form<br><input type="checkbox"/> Fee Attached<br><input type="checkbox"/> Amendment/Reply<br><input type="checkbox"/> After Final<br><input type="checkbox"/> Affidavits/declaration(s)<br><input checked="" type="checkbox"/> Extension of Time Request<br><input type="checkbox"/> Express Abandonment Request<br><input type="checkbox"/> Information Disclosure Statement<br><input type="checkbox"/> Certified Copy of Priority Document(s)<br><input type="checkbox"/> Reply to Missing Parts/<br>Incomplete Application<br><input type="checkbox"/> Reply to Missing Parts<br>under 37 CFR 1.52 or 1.53 | <input type="checkbox"/> Drawing(s)<br><input type="checkbox"/> Licensing-related Papers<br><input type="checkbox"/> Petition<br><input type="checkbox"/> Petition to Convert to a<br>Provisional Application<br><input type="checkbox"/> Power of Attorney, Revocation<br>Change of Correspondence Address<br><input type="checkbox"/> Terminal Disclaimer<br><input type="checkbox"/> Request for Refund<br><input type="checkbox"/> CD, Number of CD(s) _____<br><input type="checkbox"/> Landscape Table on CD | <input type="checkbox"/> After Allowance Communication to TC<br><input type="checkbox"/> Appeal Communication to Board<br>of Appeals and Interferences<br><input checked="" type="checkbox"/> Appeal Communication to TC<br>(Appeal Notice, Brief, Reply Brief)<br><input type="checkbox"/> Proprietary Information<br><input type="checkbox"/> Status Letter<br><input type="checkbox"/> Other Enclosure(s) (please identify<br>below): |
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Remarks

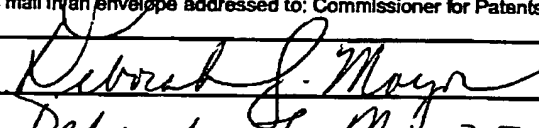
## SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	National Starch and Chemical Company		
Signature			
Printed name	David P. LeCroy		
Date	22 July 2005	Reg. No.	37,869

## CERTIFICATE OF TRANSMISSION/MAILING

591-273-8320

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1460, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Deborah J. Monzon	Date	7/22/05

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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CENTRAL FAX CENTER

JUL 22 2005

PTO/SB/17 (12-04v2)

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Effective on 12/08/2004.  
Fees pursuant to the Consolidated Appropriations Act, 2005 (H.R. 4818).**FEE TRANSMITTAL**  
For FY 2005☐ Applicant claims small entity status. See 37 CFR 1.27

TOTAL AMOUNT OF PAYMENT (\$) 2,090.00

**Complete If Known**

Application Number	09/873,505
Filing Date	June 4, 2001
First Named Inventor	CAO, Hongjie et al.
Examiner Name	YU, Gina C.
Art Unit	1617
Attorney Docket No.	1928.PC

**METHOD OF PAYMENT (check all that apply)**
☐ Check ☐ Credit Card ☐ Money Order ☐ None ☐ Other (please identify): \_\_\_\_\_

☒ Deposit Account Deposit Account Number: 14-0455 Deposit Account Name: National Starch & Chemical

For the above-identified deposit account, the Director is hereby authorized to: (check all that apply)

☒ Charge fee(s) indicated below ☐ Charge fee(s) indicated below, except for the filing fee  
☒ Charge any additional fee(s) or underpayments of fee(s) under 37 CFR 1.16 and 1.17 ☒ Credit any overpayments

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**FEE CALCULATION****1. BASIC FILING, SEARCH, AND EXAMINATION FEES**

Application Type	FILING FEES		SEARCH FEES		EXAMINATION FEES		Fees Paid (\$)
	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	Fee (\$)	Small Entity Fee (\$)	
Utility	300	150	500	250	200	100	
Design	200	100	100	50	130	65	
Plant	200	100	300	150	160	80	
Reissue	300	150	500	250	600	300	
Provisional	200	100	0	0	0	0	

**2. EXCESS CLAIM FEES**

Fee Description	Fee (\$)	Small Entity Fee (\$)
Each claim over 20 (including Reissues)	50	25
Each independent claim over 3 (including Reissues)	200	100
Multiple dependent claims	360	180
<b>Total Claims</b>		
- 20 or HP = _____ x _____ = _____		
HP = highest number of total claims paid for, if greater than 20.		
<b>Indep. Claims</b>		
- 3 or HP = _____ x _____ = _____		
HP = highest number of independent claims paid for, if greater than 3.		

**3. APPLICATION SIZE FEE**

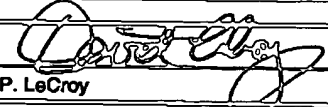
If the specification and drawings exceed 100 sheets of paper (excluding electronically filed sequence or computer listings under 37 CFR 1.52(e)), the application size fee due is \$250 (\$125 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s).

Total Sheets	Extra Sheets	Number of each additional 50 or fraction thereof	Fee (\$)	Fees Paid (\$)
_____ - 100 = _____ / 50 = _____ (round up to a whole number) x _____ = _____				

**4. OTHER FEE(S)**

Non-English Specification, \$130 fee (no small entity discount)	Fees Paid (\$)
Other (e.g., late filing surcharge): <u>Appeal Brief, Petition for Extension of Time - 4 Months</u>	\$2,090.0

**SUBMITTED BY**

Signature		Registration No. (Attorney/Agent) 37,869	Telephone 908-685-5433
Name (Print/Type)	David P. LeCroy	Date	22 July 2005

This collection of information is required by 37 CFR 1.138. This information is required to obtain or retain a benefit by the public which is to be (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 30 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Mail Stop Appeal Brief - Patents  
Appeal Brief Under 37 C.F.R. § 41.37PATENT APPLICATION  
Attorney Docket No. 1928.PC

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: CAO, Hongie *et al.*


SERIAL NO.: 09/873 505      GROUP ART UNIT: 1617

FILED: 4 June 2001      EXAMINER: YU, Gina C.

ENTITLED: STARCH-OIL COMPOSITES FOR USE IN PERSONAL CARE APPLICATIONS

CERTIFICATE of TRANSMITTAL UNDER 37 C.F.R. § 1.8

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Deborah Mouzon

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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

Dear Sir:

In compliance with the requirements of 37 C.F.R. § 41.37(c), Appellants respectfully submit their brief in furtherance of the Notice of Appeal, which was transmitted to the United States Patent and Trademark Office on 25 January 2005.

**I. REAL PARTY IN INTEREST**

National Starch and Chemical Investment Holding Corporation is the owner of the entire right, title and interest in and to the invention described in this patent application by virtue of an Assignment from the inventors, which Assignment was recorded in the United States Patent and Trademark Office on 4 June 2001 at Reel 011926, Frame 0833.

**II. RELATED APPEALS AND INTERFERENCES**

With respect to all other prior and/or pending appeals, interferences or judicial proceedings that will directly affect or be directly affected by or have a bearing on the Board's decision in this appeal, there are no such appeals or interferences known to Appellant, Appellant's legal representative or assignee.

**III. STATUS OF CLAIMS**

Claims 26-48 are pending in this application. Claims 26-48 stand rejected. Claims 1-25 have been canceled. No claims have been allowed.

The claims on appeal are Claims 26-48, which are set forth in the attached Claims Appendix.

**IV. STATUS OF AMENDMENTS**

All claims stand as amended in Applicant's Reply of 8 June 2004, and as entered in the Examiner's Action of 25 August 2004. Claims 26, 32, 39 and 46 were amended subsequent to the final rejection to strike the outlining in those claims.

**V. SUMMARY OF CLAIMED SUBJECT MATTER**

The following summary of the subject matter defined in each of the independent claims involved in the Appeal is offered to enable the Board to more quickly determine where in the application enabling embodiments of the claimed subject matter are described. However, because other embodiments may fall within the scope of the claims, this summary should not be construed as limiting of the claims hereafter discussed.

Claims 26, 32, 39 and 46 are the pending independent claims, with claims 27-3 depending directly from claim 26, claim 33-38 depending directly from claim 32, claims 40-45 depending directly from claim 39, and claims 47 and 48 depending directly from claim 46. For ease of reference, claim 32 and 46 are as follows –

21. A stable, aqueous personal care or cosmetic formulation comprising:

- a) a cationic starch-encapsulated hydrophobic material; and
- b) water,

wherein said starch-encapsulated hydrophobic material is essentially non-separable in said personal care or cosmetic aqueous formulation and the formulation is surfactant-free.

46. A method for applying one or more cosmetic or personal care active ingredients to the skin or hair comprising:

- a) forming a surfactant-free, stable, aqueous personal care or cosmetic formulation comprising a cationic starch-encapsulated hydrophobic material containing a personal care or cosmetic active ingredient, wherein said starch-encapsulated material is essentially non-separable in said personal care or cosmetic aqueous formulation; and
- b) applying said personal care or cosmetic formulation to the skin or the hair, whereby the starch-encapsulated material is broken by mechanical energy to release the active ingredient onto the skin or hair

Claim 26 differs from claim 32 only in that it further defines the hydrophobic material as further including a sun-screen active ingredient (Specification: p. 4, lines 24-25). Claim 39 differs from claim 32 only in that it further defines the stable, aqueous formulation as further including a preservative (Specification: Example 5).

From the above independent claim 32 it is seen that the present invention is generally directed towards a stable, aqueous formulation having at least a cationic starch-encapsulated hydrophobic material and water. In contrast to the art, the starch-encapsulated hydrophobic

material is essentially non-separable in the aqueous formulation, meaning the encapsulant with the active ingredient therein remain intact in the aqueous formulation (*i.e.*, does disperse out in the water) (Specification: p. 2, lines 6-8 and 12-18) and the formulation is surfactant-free (Specification: p. 5, lines 6-7). Aqueous formulations are defined as those formulations having at least one percent by weight of water (Specification: p. 4, lines 14-29). Hydrophobic materials include "hydrophobic compounds or other water soluble materials known in the art for use in personal care and cosmetic applications" (Specification: p. 3, lines 8-17). The starch-based encapsulant is cationically modified (Specification: p. 2, line 27 – p. 3, line 7; p. 5, line 29 – p. 6, line 3).

With reference to independent claim 46 it is seen that the present invention is also directed towards a method of applying one or more active ingredients to skin or hair. This is accomplished by forming a surfactant-free, stable, aqueous formulation having therein a cationic starch-encapsulated hydrophobic material containing a personal care or cosmetic active ingredient, wherein the starch-encapsulated material is essentially non-separable in the aqueous formulation (Specification: p. 2, lines 9-11). The formulation is then applied to the skin or hair, and, with the use of mechanical energy, the active is separated or released from the starch-encapsulated material onto the hair or skin (Specification: p. 2, lines 17-19; p. 6, lines 16-18).

As previously pointed out, the foregoing summary of the invention has been provided only for purposes of aiding the Board in locating at least an exemplary embodiment of the claimed subject matter within the specification. However, it is also understood that other possible embodiments as may exist within the specification may have been omitted. Compliance with this requirement, therefore, should not be applied to limit the claims.

## VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The grounds of rejection presented for in this Appeal are:

- (a) Claims 32-35, 39-42 and 46-48 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,676,994 to Eskins *et al.* ("Eskins") in view of U.S. Patent No. 6,340,527 to Van Soest ("Van Soest"), U.S. Patent No. 5,676,994 to Fletcher *et al.* ("Fletcher"), or Robert L. Goldemberg, Society of Cosmetic Chemists,

*Drug & Cosmetic Industry*, Vol., 159, No. 2, pp. 50-53 (New York, Aug. 1996) ("Goldemberg").

- (b) Claims 26-28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Eskins in view of Van Soest, Fletcher and Goldemberg as applied to claims 32-35, 39-42 and 46-48 above, and further in view of U.S. Patent No. 6,362,146 to Macaulay ("Macaulay").
- (c) Claims 29-31, 36-38 and 43-45 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Eskins in view of Van Soest, Fletcher, Goldemberg and Macaulay as applied to claims 26-28, 39-42 and 46-48 above, and further in view of the publication Ashley, *Sunburn and Sunscreen Preparations*, Poucher's Perfumes, Cosmetics and Soaps ("Ashley").

## VII. APPELLANT'S ARGUMENTS

- A. REJECTION UNDER 35 U.S.C. § 103(a) AS BEING UNPATENTABLE OVER U.S. PATENT NO. 5,676,994 TO ESKINS *et al.* IN VIEW OF U.S. PATENT NO. 6,340,527 TO VAN SOEST, U.S. PATENT NO. 5,676,994 TO FLETCHER *et al.*, OR ROBERT L. GOLDEMBERG, SOCIETY OF COSMETIC CHEMISTS, *DRUG & COSMETIC INDUSTRY*, VOL. 159, NO. 2, pp. 50-53 (NEW YORK, AUG. 1996).

Claims 32-35, 39-42 and 46-48 stand rejected as being unpatentable over Eskins in view of Van Soest, Fletcher or Goldemberg. Specifically, the Examiner states –

Claimed invention is a surfactant-free aqueous composition comprising "cationic starch encapsulated hydrophobic material" containing an active ingredient. The starch encapsulated hydrophobic material is said to be non-separable.

Eskins teaches non-separable starch-oil compositions useful for food, agriculture, or pharmaceutical and cosmetic carriers or vehicles, which meets the "starch encapsulated hydrophobic material" limitation. See col. 13, lines 55-63; col. 11, lines 60-66; instant claims 32, 39, 46. The abstract teaches that the composition is prepared in the absence of external emulsifying or dispersing agents. The reference teaches "the presence of the oil component in [the starch-oil-water] composition causes them to function as emulsifying and dispersing agents and makes them receptive to the addition of a variety of water-immiscible materials, for example, additional lipid, volatile, and essential oils and food flavoring materials, antioxidants, medicinal agents, agricultural chemicals". See col. 5, lines 40-53. The application of the starch-encapsulated actives in cosmetic formulations includes body and hand lotions, cream, and suntan lotion. Examples also illustrate encapsulating soybean oil. See instant claims 39 and 47. Example

13 teaches a dispersion of 300 g of soybean oil in 3 liters of water, which constitutes 10 % by weight. See instant claims 35, and 42. The method of topically applying the topical composition is an obvious use of the composition. See instant claims 46-48.

It is noted that claims 34, 41 and 48 are product-by-process claims, where only the limitation to the composition itself is given patentable weight. See MPEP § 2113. Eskins nonetheless teaches that the invention is prepared by jet cooking the starch. See col. 8, line 64 – col. 13, line 21.

Eskins fails to teach cationic starch.

Van Soest teaches that cationic starch is well known encapsulating material for hydrophobic or water insoluble solid active ingredients. See col. 1, line 36 – col. 2, line 11.

Fletcher et al. teach viscous antiperspirant aqueous emulsions comprising amphoteric or cationic modified starch. See abstract; col. 1, line 7 – col. 35; col. 7, lines 6-30. The reference teaches that the compositions exhibit excellent phase stability even in the high concentrated antiperspirant salts in the solution and elevated storage temperature. See col. 2, line 53 – col. 19, line 22.

Goldemberg teaches that it is well known in cosmetic art to employ cationic modified starch to entrap and stabilize antioxidants in a cosmetic composition. See page 2, 6<sup>th</sup> full par.

Given the teaching of starch encapsulants for cosmetic ingredients in Eskins, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have looked to the prior arts such as an Soest, Fletcher, and Goldemberg for specific type of starch and used cationic starch as motivated by the teachings of these references because of the expectation of successfully producing a stable cosmetic composition. . . .

. . . . Applicant's arguments are generally directed to the deficiencies of each reference. It is respectfully pointed out that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cr. 1986).

Applicants assert that the teachings of Eskins is limited to "unmodified starch". The reference in fact teaches, "modified starches may be used, however, to prepare compositions of this invention, if certain properties are desired that are not obtainable with unmodified starches". See Eskins, col. 6, lines 31-41. Thus the emulsifier-free emulsion of Eskins also uses modified starches. The reference also states, "modified starch does not have the sticky, gummy properties of unmodified starch and also functions as an emulsion stabilizer". See Eskins col. 3, lines 55-65 (referring to the Hermansson patent). Thus it is well known in the art that emulsifier-free emulsion can be made with modified starch, as applicants have done in the present case.



The presence of surfactants in the Van Soest composition does not negate the teaching of the Eskins that modified starches stabilize emulsifier-free emulsion. While applicants argue that Van Soest invention is limited to using granular type of starch, examiner notes that the claims do not distinguish whether the starch is granular or non-granular. If the starch produced by jet cooking necessarily is non-granular type, it must be noted that the inventions in Claims 26, 28-47 do not require non-granular type of starches. Nowhere in the Van Soest indicates that granular type of starches is the only starch suitable for the invention. Furthermore, using modified starches produced by jet steam cooking is well known in the art, as evidenced by Eskins.

Applicants assert that Fletcher is not combinable with Eskins and Van Soest because former allegedly fails to teach aqueous formulation. The arguments are not persuasive as the Fletcher reference in fact teaches that the cationic modified starch is added in the aqueous phase of the emulsion to form a viscous [*sic*, viscous] emulsion. See abstract.

Applicants further argues that the prior art is limited to using hydrophilic active ingredients and that the prior art uses surfactants in the composition. Applicants make analogous arguments against applying Goldemberg. In response, examiner reiterates that it is Eskins which provides the teaching that modified starches can stabilize emulsion without the aid of emulsifiers. Encapsulating hydrophobic active compounds with modified starches is also taught by the primary reference.

While applicants assert that the rejection is a hindsight reconstruction made with numerous references, examiner respectfully points out that reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991). In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, all the evidence used to make the necessary motivation to combine the references are taught in the references. Examiner asserts that no impermissible hindsight was used to make the rejections. . . .

Applicants assert that a skilled artisan would not have found it obvious to combine Van Soest with Eskins because the former teaches "crosslinked cationic starch granules for use as encapsulating material" as opposed to "cooked-out starch". In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The idea of using starch to encapsulate hydrophobic

materials without the use of surfactant is well known in the art, as evidenced by Eskins. The issue here is whether it would have been obvious to the routineer to use cationic starch to make the starch encapsulating material as taught by Eskins. Van Soest and Fletch teach that cationic starch is used as a controlled-release encapsulating material. Applicants' remarks regarding the Goldemberg reference was considered, but it does not negate the fact that cationically modified starch is used as a controlled-release carrier in cosmetic art.

#### 1. The Standard for Obviousness

As the Federal Circuit has stated, "[t]he test of obviousness *vel non* is statutory". *In re Ochiai*, 71 F.3d 1565, 1569 (Fed. Cir. 1995). In order to sustain the Examiner's rejections, this Board must find that the *claimed* subject matter, taken "as a whole", would have "been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains". 35 U.S.C. § 103(a).

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991).

"There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper.). The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

"In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be

sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab*, 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

## 2. The Scope and Content of the Prior Art

Eskins discloses a process for preparing stable and non-separable compositions of starch and oil without the use of external emulsifying or dispersing agents (Abstract; col. 5, lines 21-25). These compositions are prepared by gelatinizing (cooking) starch in the presence of water under conditions that completely solubilize the starch, and then mixing the oil in the starch/water solution under conditions of high turbulence before the starch can retrograde (col. 5, lines 25-29; col. 7, line 60 – col. 10, line 28). The products of Eskins are recovered under conditions that stabilize the distribution of the oil in the starch phase, *i.e.*, allowing the emulsion to cool below 100°C or lower prior to drying (col. 9, lines 54-64). Once cooled, the starch/oil/water dispersion can optionally be dried (col. 11, lines 7-9). Preferably, drum drying is used to dry the dispersion (col. 11, lines 11-13), although other drying techniques can be used as long as the cooked dispersion is allowed to cool below 100°C while still in the form of a fluid aqueous dispersion (col. 11, lines 21-27). These dried dispersions are easily redispersed in water to form smooth, stable dispersions (Abstract).

The compositions of Eskins are preferably prepared from unmodified starch (*i.e.*, one that has not been altered by chemical treatment or reduced in molecular weight (degraded) by reaction with acids or enzymes (col. 6, lines 26-28)), although modified starch can be used (col. 6, lines

17-20 and 31-34). Eskins provides no guidelines as to what types of chemically modified or degraded starches can be used or whether further modification to the process is required when such a modified starch is employed (*e.g.*, addition of a surfactant), and only exemplifies unmodified starches. The 'oil' of Eskins interchangeably refers to lipids, fats and oil, with vegetable oils, animal fats and mineral oils preferred (col. 7, lines 1-14).

Eskins teaches that its compositions are suitable for use in food formulations (col. 11, lines 46-59; col. 12, lines 5-14). Eskins further suggests that its compositions are useful as carriers for pharmaceutical, cosmetic and personal care formulations such as sun tan lotions, as well as carriers for agricultural actives; however, Eskins provides no exemplification of such applications (col. 11, line 60 – col. 12, line 5 and 15-20).

Eskins is cited in the 'Background' and 'Detailed Description' portion of the present description as disclosing a process for preparing stable, water-insoluble starch-oil compositions formed by jet cooking a mixture of starch and other ingredients.

Van Soest teaches another process for encapsulating active ingredients in a crosslinked starch shell (Abstract). According to the process of Van Soest, oil or another hydrophobic substance is added to an aqueous solution or dispersion of starch (col. 2, lines 52-54). If the active ingredient is also hydrophobic, it can be added with the oil (col. 1, lines 36-51; col. 2, lines 58-59). Preferably, a surfactant is added to the aqueous dispersion before the hydrophobic substance is added (col. 2, lines 61-63). Crosslinking is brought about by the addition of a crosslinking agent to the aqueous dispersion of starch (col. 3, lines 33-35).

Once a stable oil-in-water emulsion is achieved, it is dispersed in a hydrophobic ('oil') phase, thereby forming an oil-in-water-in-oil emulsion (col. 3, lines 6-14). Another surfactant can be added to this second phase for promoting the water-in-oil emulsion (col. 3, lines 14-16). Crosslinking can occur at any desired point in the process, preferably after formation of the oil-in-water-in-oil emulsion, by addition of a catalyst or raising the temperature of the emulsion (col. 3, lines 35-41).

"Suitable starches are native starch and fractions and derivatives thereof. Preferably, the starch is a granular starch" (col. 1, lines 55-58). Starch derivatives refer to modified granular starches and include oxidized starch, carboxyalkylated starch, sulfated or phosphated (cationic) starch (col. 1, line 59 – col. 2, line 11). Further, it is well known in the art to crosslink starch

granules so that they are only partially or completely insoluble in water, solubility being controlled based upon the degree of crosslinking. Such crosslinked starch granules are typically used in the art as thickeners. According to Van Soest, the use of granular starches has advantages over soluble starches, including the degree of gelatinization (*i.e.*, thickening) (col. 2, lines 12-32).

Fletcher teaches antiperspirant compositions formed from a dispersion of a hydratable polymer such as a cationic starch in an aqueous emulsion that is subjected to high shear, agitating the emulsion, and introducing an antiperspirant salt into the emulsion to form the inventive antiperspirant emulsion (Abstract; col. 2, lines 52-67). The emulsion is formed from an aqueous phase and an oil phase with an emulsifier in at least one of the two phases (col. 5, lines 38-40). The starch is added to thicken the emulsion, with the amount of starch added varying based on particular application (col. 8, lines 10-24; *see also*, col. 3, lines 20-44; col. 5, lines 9-15). Fletcher does not teach or suggest starch encapsulation, nor does it teach or suggest the use of its cationically modified granular starches as an encapsulating material. Rather, Fletcher is directed towards the formation of stable oil-in-water emulsions that remain stable when a hydrophilic salt is added to the emulsion. Accordingly, one skilled in the art would not look to the cationic granular, thickening starch of Fletcher as being useful as a cooked-out modified starch in the process of Eskins.

Goldemberg discloses entrapment of free radical scavengers in glycospheres having a cationically modified starch core. The scavengers are anionic hydrophilic constituents (here, extracts of the polyphenols nutgall and green tea) that are entrapped or retained on the core. (It is believed that this entrapment is due to ionic bonding.) Goldemberg does not teach or suggest starch encapsulation of a hydrophobic material; rather, Goldemberg teaches glycospheres having a polysaccharide core or center. Goldemberg only teaches entrapment of hydrophilic materials as opposed to hydrophobic materials, and further does not teach starch encapsulation of a hydrophobic material.

### 3. The Claims of the Present Invention are not obvious

As noted in the 'Summary of the Claimed Subject Matter' above, the starch-encapsulated hydrophobic material of the present invention is essentially non-separable in an aqueous

formulation, meaning the encapsulant with the active ingredient therein remains intact in the aqueous formulation (*i.e.*, does disperse out in the water) (Specification: p. 2, lines 6-8 and 12-18). Therefore, in order for the claimed any of the references to render claims 32-35, 39-42 and 46-48 obvious, they must teach or suggest, alone or in combination, this limitation.

The Examiner refers to Eskins as the primary reference. Eskins teaches non-separable starch-oil compositions that form a smooth, stable dispersion when added to water. In contrast, when the starch-encapsulated hydrophobic material of the present invention is added to an aqueous-based formulation, it does not disperse into the water but rather remains non-separable as a suspension (*i.e.*, remains encapsulated) (see, *e.g.*, Specification: p. 4, lines 9-13; Example 2 stating that the “encapsulation particles can be suspended in clear skin or hair care products” to provide a visual effect). In order for Eskins to provided motivation to one skilled in the art to seek for such a starch-encapsulated hydrophobic material, Eskins must provide some teaching, suggestion, or motivation for its starch-oil composition to remain encapsulated when added to water. However, Eskins seeks to provide a solution to the problem of providing an edible starch-based composition having a continuous aqueous phase and a dispersed oil phase, wherein the composition does not separate into an aqueous layer and a separate oil layer when left standing (col. 1, lines 20-24). In doing so, Eskins provides a jet cooked starch solution that, when dried, hydrates rapidly so that it readily redisperses in water, yielding lump-free pastes having the smooth consistency required for food applications (col. 2, lines 23-26; col. 5, lines 29-40). In fact, Eskins specifically states that the “products of this invention are distinguished from ‘encapsulated’ oils wherein relatively large drops of oil are encased within a protective layer of starch” (col. 8, lines 51-53). Accordingly, Eskins by its own admission is not directed towards the type of product that the present invention provides. As such, Eskins does not teach or suggest cationic starch-encapsulated hydrophobic materials that are non-separable in aqueous formulation, and specifically teaches away from seeking such a product.

Van Soest teaches the use of crosslinked, cationic starch granules for use as encapsulating material. Eskins, as admitted by the Examiner, fails to teach cationic starch. The Examiner refers to Van Soest for its teachings of cationic starch. As previously indicated, Eskins states that modified starches can be used as its starch-based component; however, Eskins provides no further guidelines as to what types of modified starches would be suitable (in particular, no

reference is made to cationic starches), and only exemplifies the use of non-modified starches. Accordingly, it is specious at best to state that one skilled in the art, having Eskins before him, would be motivated to look to Van Soest for the use of its cationic starches granules in the jet-cooking process of Eskins to form the solubilized or cooked-out starch constituent of Eskins. Further, even if one skilled in the art were motivated to look to Van Soest for the suggestion to use cationic starch (and Applicant is not implying that this is the case), one still would not predict from the teachings of Eskins that use of such a starch would provide the non-separable starch-encapsulated hydrophobic product of the present invention. Rather, one skilled in the art would believe that the cationic starch would hydrate rapidly so that it readily redisperses in water.

Like Van Soest, the Examiner refers to Fletcher for its teachings of the use of cationic starches. However, Fletcher only serves to further teach away from the present invention in that it teaches dispersing cationic starch into an emulsion containing an emulsifier (*i.e.*, surfactant; see, col. 12, lines 1-59). In contrast, the present formulation is surfactant-free. Therefore, even if one skilled in the art were to take the cationic starch of Fletcher and use it in the starch-oil composition of Eskins, one skilled in the art would be lead to believe that a surfactant must also be added in order for a stable emulsion to be formed.

The Examiner refers to Goldemberg for teaching that "it is well known in cosmetic art to employ cationic modified starch to entrap and stabilize antioxidants in a cosmetic composition". Goldemberg does not teach or suggest starch encapsulation of a hydrophobic material; rather, Goldemberg teaches glycospheres having a polysaccharide core or center. Goldemberg only teaches entrapment of hydrophilic materials as opposed to hydrophobic materials, and further does not teach starch encapsulation of a hydrophobic material. Accordingly, Goldemberg adds nothing to Eskins.

Accordingly, none of the cited references, alone or in combination, teach or suggest this cationic-starch encapsulated hydrophobic material that is non-separable in a surfactant-free, aqueous formulation, as claimed in independent claims 32, 39 and 46 of the present application, and therefore their corresponding dependent claims. Therefore, the rejection of claims 32-35, 39-42 and 46-48 as being unpatentable over Eskins in view of Van Soest, Fletcher or Goldemberg is without merit and should be overturned.

B. REJECTION UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER ESKINS IN VIEW OF VAN SOEST, FLETCHER AND GOLDEMBERG AS APPLIED TO CLAIMS 32-35, 39-42 AND 46-48 ABOVE, AND FURTHER IN VIEW OF U.S. PATENT NO. 6,362,146 TO MACAULAY ("MACAULAY").

The Examiner has rejected claims 26-28 as being unpatentable over Eskins in view of Van Soest, Fletcher and Goldemberg as applied to claims 32-35, 39-42 and 46-48 above, and further in view of U.S. Patent No. 6,362,146 to Macaulay ("Macaulay"). Specifically, the Examiner states –

The combined references fail to teach sunscreen active ingredients.

Macaulay teaches that encapsulated sunscreens are known in the art. See col. 6, lines 4-25. The reference further teaches a water-based cleansing composition comprising 2, 5, and 10% of the encapsulated sunscreen actives. See Example 1; instant claims 27 and 42.

Given the teaching of the cosmetic application of the starch-encapsulated active ingredients in Eskins, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have added sunscreen actives in the active ingredients as motivated by Macaulay, because of the expectation of successfully producing controlled-release sunscreen compositions. . . .

. . . . Applicants also assert that Macaulay does not teach or suggest starch encapsulation of sunscreen actives, and that there is no objective teaching that sunscreen actives per se can be starch encapsulated based on the teachings of Macaulay. In response, examiner notes that Macaulay is not the only reference that is cited to provide the basis of the obviousness rejection. The idea of encapsulating hydrophobic skin care actives in starch for the purpose of controlled-release is taught by Eskin. The rejection is based on the collective teachings of the cited references.

For the following reasons, Applicants respectfully traverse the Examiner's rejection of claims 26-28 as being unpatentable over Eskins in view of Van Soest, Fletcher and Goldemberg as applied to claims 32-35, 39-42 and 46-48 above, and further in view of Macaulay.

1. The Scope and Content of the Prior Art

Eskins, Van Soest, Fletcher and Goldemberg were discussed previously, those arguments being incorporated herein.

Macaulay teaches personal washing compositions that include a surfactant, a polymeric deposition aid, and an encapsulated sunscreen (Abstract). According to Macaulay, the



encapsulated sunscreen is a combination of an organic sunscreen active that is trapped within a wax or oil matrix (col. 6, lines 4-18). The encapsulant is supplied as an emulsion in an aqueous or oil carrier, depending upon the nature of the sunscreen active (col. 6, lines 18-25). Macaulay does not teach or suggest starch encapsulation of its sunscreen actives. Further, Macaulay recognizes that the nature of the active can affect the emulsion used; therefore, it cannot objectively be said that sunscreen actives per se can be starch encapsulated based upon the teachings of Macaulay.

2. The Claims of the Present Invention are not obvious

The Examiner refers to Macaulay for teaching encapsulation of sunscreen actives. Firstly, Eskins provides no motivation to one skilled in the art to seek use of its starch-oil compositions for encapsulation of sunscreen actives. Secondly, even if one were to suggest the combination of Eskins and Macaulay, one still would not have the non-separable cationic-starch encapsulated hydrophobic material of the present invention. Instead, only a dispersion of the sunscreen actives would be provided. Therefore, Macaulay adds nothing to Eskins.

Accordingly, none of the cited references, alone or in combination, teach or suggest this cationic-starch encapsulated hydrophobic material that is non-separable in a surfactant-free, aqueous formulation, as claimed in independent claim 26 of the present application, and therefore its corresponding dependent claims. Therefore, the rejection of claims 26-28 as being unpatentable over Eskins in view of Van Soest, Fletcher and Goldemberg as applied to 32-35, 39-42 and 46-48 above and further in view of Macaulay is without merit and should be overturned.

- C. REJECTED UNDER 35 U.S.C. § 103(A) AS BEING UNPATENTABLE OVER ESKINS IN VIEW OF VAN SOEST, FLETCHER, GOLDEMBERG AND MACAULAY AS APPLIED TO CLAIMS 26-28, 39-42 AND 46-48 ABOVE, AND FURTHER IN VIEW OF THE PUBLICATION ASHLEY, *SUNBURN AND SUNSCREEN PREPARATIONS*, POUCHER'S PERFUMES, COSMETICS AND SOAPS ("ASHLEY").

The Examiner has rejected claims 29-31, 36-38 and 43-45 as being unpatentable over Eskins in view of Van Soest, Fletcher, Goldemberg and Macaulay as applied to claims 26-28, 39-42 and 46-48 above, and further in view of the publication Ashley, *Sunburn and Sunscreen Preparations*, Poucher's Perfumes, Cosmetics and Soaps ("Ashley"). Specifically, the Examiner states –

The combined references fail to teach the water content in the cosmetic compositions as required by the instant claims.

1. The Scope and Content of the Prior Art

Eskins, Van Soest, Fletcher, Goldemberg and Macauley were discussed previously, those arguments being incorporated herein.

Ashley teaches oil/water and water/oil emulsions in the form of creams and lotions. These compositions require emulsifiers or surfactants for particle stability.

2. The Claims of the Present Invention are not obvious

Ashley is cited by the Examiner for teaching the water content in cosmetic compositions and for no other reason. Eskins provides no guidelines regarding water content in its dispersion other than provided in the Examples. Ashley does not teach aqueous cosmetic formulations containing starch encapsulated ingredients. Therefore, it cannot be said that Ashley provides guidelines for water content in cosmetic compositions according to the present invention or Eskins. Further, the compositions of the present invention are surfactant-free. Therefore, one skilled in the art would not look to Ashley for water content in the starch-oil compositions of Eskins.

Accordingly, none of the cited references, alone or in combination, teach or suggest this cationic-starch encapsulated hydrophobic material that is non-separable in a surfactant-free, aqueous formulation, as claimed in independent claims 26, 32, 39 and 46 of the present application, and therefore its corresponding dependent claims. Therefore, the rejection of claims 29-31, 36-38 and 43-45 as being unpatentable over Eskins in view of Van Soest, Fletcher, Goldemberg and Macaulay as applied to claims 26-28, 39-42 and 46-48 above, and further in view of Ashley is without merit and should be overturned.

**VIII. CONCLUSION**

For the reasons mentioned above, Appellant's aqueous formulation containing a cationic starch-encapsulated hydrophobic material, and the method for applying it to skin or hair is not made obvious over the art as none teach a cationic starch-encapsulated hydrophobic material that does not disperse out in the aqueous formulation. Therefore, the Examiner has failed to establish a *prima facie* case of obviousness under 35 U.S.C. § 103(a) of any of claims 26-48. Accordingly, the rejections under 35 U.S.C. § 103(a) should be reversed

For all of the foregoing reasons, it is respectfully submitted that the final rejection of all claims is untenable and should not be sustained. Allowance of the claims is believed to be in order, and such allowance is respectfully requested.

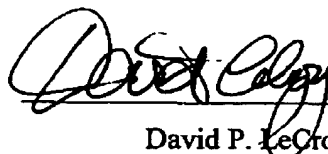
Respectfully submitted,

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## **CLAIMS APPENDIX**

### **Claims of U.S. Application No. 09/873 505 on Appeal**

1-25 (Cancelled)

26. (Previously presented) A stable, aqueous personal care or cosmetic formulation comprising:
- a) a cationic starch-encapsulated hydrophobic material, wherein said hydrophobic material comprises a sun-screen active ingredient; and
  - b) water,
- wherein said starch-encapsulated hydrophobic material is essentially non-separable in said personal care or cosmetic aqueous formulation and the formulation is surfactant-free.
27. (Previously presented) The aqueous formulation of claim 26, wherein said starch-encapsulated hydrophobic material is formed by jet cooking a mixture of the starch and the hydrophobic material.
28. (Previously presented) The aqueous formulation of claim 26 comprising from 0.5 to 25 percent by weight of said starch-encapsulated hydrophobic material.
29. (Previously presented) The aqueous formulation of claim 26 comprising at least 10 percent by weight of water.
30. (Previously presented) The aqueous formulation of claim 26 comprising at least 20 percent by weight of water.
31. (Previously presented) The aqueous formulation of claim 26 comprising at least 40 percent by weight of water.

32. (Previously presented) A stable, aqueous personal care or cosmetic formulation comprising:
- a) a cationic starch-encapsulated hydrophobic material;
  - b) water,
- wherein said starch-encapsulated hydrophobic material is essentially non-separable in said personal care or cosmetic aqueous formulation and the formulation is surfactant-free.
33. (Previously presented) The aqueous formulation of claim 32 wherein said hydrophobic material is selected from the group consisting of mineral oils, oils of plant and animal origin, synthetic oils, fats, lipids, fatty acids, fatty alcohols, esters, ethers, wax, jojoba oil, soybean oil, silicones, vitamins, vitamin A, vitamin D, vitamin E, and vitamin K, fragrances, emollients, petrolatum, pigments, water-insoluble polymers, anti-perspirants, sun screen actives, benzophenone-3 (oxybenzone), octyl methoxy cinnamate, water insoluble solvents, insect repellants, and mixtures thereof.
34. (Previously presented) The aqueous formulation of claim 32, wherein said starch-encapsulated hydrophobic material is formed by jet cooking a mixture of the starch and the hydrophobic material.
35. (Previously presented) The aqueous formulation of claim 32 comprising from 0.5 to 25 percent by weight of said starch-encapsulated hydrophobic material.
36. (Previously presented) The aqueous formulation of claim 32 comprising at least 10 percent by weight of water.
37. (Previously presented) The aqueous formulation of claim 32 comprising at least 20 percent by weight of water.
38. (Previously presented) The aqueous formulation of claim 32 comprising at least 40 percent by weight of water.

39. (Previously presented) A stable, aqueous personal care or cosmetic formulation comprising:

- a) a cationic starch-encapsulated hydrophobic material;
- b) a preservative; and
- c) water,

wherein said starch-encapsulated hydrophobic material is essentially non-separable in said personal care or cosmetic aqueous formulation and the formulation is surfactant-free.

40. (Previously presented) The aqueous formulation of claim 39 wherein said hydrophobic material is selected from the group consisting of mineral oils, oils of plant and animal origin, synthetic oils, fats, lipids, fatty acids, fatty alcohols, esters, ethers, wax, jojoba oil, soybean oil, silicones, vitamins, vitamin A, vitamin D, vitamin E, and vitamin K, fragrances, emollients, petrolatum, pigments, water-insoluble polymers, anti-perspirants, sun screen actives, benzophenone-3 (oxybenzone), octyl methoxy cinnamate, water insoluble solvents, insect repellants, and mixtures thereof.

41. (Previously presented) The aqueous formulation of claim 39, wherein said starch-encapsulated hydrophobic material is formed by jet cooking a mixture of the starch and the hydrophobic material.

42. (Previously presented) The aqueous formulation of claim 39 comprising from 0.5 to 25 percent by weight of said starch-encapsulated hydrophobic material.

43. (Previously presented) The aqueous formulation of claim 39 comprising at least 10 percent by weight of water.

44. (Previously presented) The aqueous formulation of claim 39 comprising at least 20 percent by weight of water.

45. (Previously presented) The aqueous formulation of claim 39 comprising at least 40 percent by weight of water.

46. (Previously presented) A method for applying one or more cosmetic or personal care active ingredients to the skin or hair comprising:
- c) forming a surfactant-free, stable, aqueous personal care or cosmetic formulation comprising a cationic starch-encapsulated hydrophobic material containing a personal care or cosmetic active ingredient, wherein said starch-encapsulated material is essentially non-separable in said personal care or cosmetic aqueous formulation; and
  - d) applying said personal care or cosmetic formulation to the skin or the hair, whereby the starch-encapsulated material is broken by mechanical energy to release the active ingredient onto the skin or hair.
47. (Previously presented) The method of claim 46, wherein said hydrophobic material is selected from the group consisting of mineral oils, oils of plant and animal origin, synthetic oils, fats, lipids, fatty acids, fatty alcohols, esters, ethers, wax, jojoba oil, soybean oil, silicones, vitamins, vitamin A, vitamin D, vitamin E, and vitamin K, fragrances, emollients, petrolatum, pigments, water-insoluble polymers, anti-perspirants, sun screen actives, benzophenone-3 (oxybenzone), octyl methoxy cinnamate, water insoluble solvents, insect repellants, and mixtures thereof.
48. (Previously presented) The aqueous formulation of claim 46, wherein said starch-encapsulated hydrophobic material is formed by jet cooking a mixture of the starch and the hydrophobic material.